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APPLICATION NO. ATTY, DOCKET NO. 4821-464 Unassigned LIST OF REFERENCES CITED BY APPLICANT P Sercon Marin P. REDMON et al. (Use several sheets if necessary) GROUP February 15, 2002 Unassigned U.S. PATENT DOCUMENTS SUBCLASS DOCUMENT NUMBER DATE AΑ 5,681,582 10/28/97 Gillis et al. 424 468 5,489,436 441 AB 02/06/96 Hoy et al. 424 11/14/95 Cutberth 548 511 AC 5,466,826 514 AD 02/01/94 224.5 5,283,243 Jasserand et al. ΑE 05/25/93 Hampton et al. 5,213,738 AF 4,835,161 05/30/89 Janssens et al. 01/24/89 AG 4,799,966 Parrish et al. 12/03/85 Janssens et al. AΗ 4,556,660 4,219,559 08/26/80 Janssens et al. AJ ΑK AL **FOREIGN PATENT DOCUMENTS** CLASS SUBCLASS TRANSLATION DOCUMENT NUMBER DATE COUNTRY YES NO WO 98/06394 WA AM 2/1998 BET WO 5/1997 AN WO 97/19074 4/1994 PCT (J) ΑO WO 94/07495 AP DE 40 37 426 A1 5/1992 Germany ΑQ EP 0 232 937 A2 08/19/87 Europe AR AS AT OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.) ΑU Physician's Desk Reference, 53rd ed., 1423-1426 (1999) Physician's Desk Reference, 52<sup>nd</sup> ed., 1303-1304 (1998) ΑV AW Blaug et al., "Interaction of Dextroamphetamine sulfate with spray-dried lactose," J. Phsrmaceutical Sciences 61:11, 1770-1775. AX Castello, "Discoloration of tablets containing amines and lactose, J. Pharm. Sciences 5:12, 106-108 AY Handbook of Pharmaceutical Excipients, Second Edition, eds. A. Wade et al., American Pharmaceutical Association Washington, pp. 252-261, 1994.

| BA "HISMANAL®" Physicians' Desk Reference, Medical Economics Co., Inc., 51st ed. (1997), pp. 1591-1591-1591-1591-1591-1591-1591-1591   |     | ĄZ | V. Kumar et al., "Maillard Reaction and Drug Stability", Maillard Reactions in Chemistry, Food, and Healpp. 21-27 (August 1993).   |  |  |  |  |  |  |
|--|-----|----|--|--|--|--|--|--|--|
| BB "HISMANAL®" Physicians' Desk Reference, Medical Economics Co., Inc., 51st ed. (1930), pp. 1830.  BC K.J. Hartauer, et al., "A Comparison of Diffuse Reflectance FT-IR Spectroscopy and DSC in the Characterization of a Drug-Excipient Interaction," Drug Development and Indus. Pharm., 17(4):617-630 (1991).  BD Kamei, et al., "Antiallergic Effects of Major Metabolites of Astemizole in Rats and Guinea Pigs," Arzneimittel Forschung, 41(11):932-936 (1991).  BE Janssens, et al., "New Antihistaminic N-Heterocyclic 4-Piperidinamines," J. Med. Chem., 28:1934-1943 (1985).  BF W. Ebert, "Soft Elastic Gelatin Capsules: A Unique Dosage Form," Pharm. Tech., 1(5):44-50 (1977).  BG S.M. Blaug, et al., "Interaction of Dextroamphetamine Sulfate with Spray-Dried Lactose," J. Pharm. Sci., 61(11):1770-1775 (1972).  BH R. Castello, et al., "Discoloration of Tablets Containing Amines and Lactose," J. Pharm. Sci., 51(2):106-108 (1962). | 24  | -  | Will Developes 'Desk Reference, Medical Economics Co., Inc., 51st ed. (1997), pp. 1541-151st   |  |  |  |  |  |  |
| BC K.J. Hartauer, et al., "A Comparison of Diffuse Reflectance FT-IR Spectroscopy and DSC in the Characterization of a Drug-Excipient Interaction," Drug Development and Indus. Pharm., 17(4):617-630 (1991).  BD Kamei, et al., "Antiallergic Effects of Major Metabolites of Astemizole in Rats and Guinea Pigs," Arzneimittel Forschung, 41(11):932-936 (1991).  BE Janssens, et al., "New Antihistaminic N-Heterocyclic 4-Piperidinamines," J. Med. Chem., 28:1934-1943 (1985).  BF W. Ebert, "Soft Elastic Gelatin Capsules: A Unique Dosage Form," Pharm. Tech., 1(5):44-50 (1977).  BG S.M. Blaug, et al., "Interaction of Dextroamphetamine Sulfate with Spray-Dried Lactose," J. Pharm. Sci., 61(11):1770-1775 (1972).  BH R. Castello, et al., "Discoloration of Tablets Containing Amines and Lactose," J. Pharm. Sci., 51(2):106-108 (1962).   | -+- |    | " UCMANIA ®" Physicians' Desk Reference, Medical Economics Co., Inc., 51st ed. (1990), pp.   |  |  |  |  |  |  |
| BD Kamei, et al., "Antiallergic Effects of Major Metabolites of Astemizole in Rats and Guinea Pigs, Arzneimittel Forschung, 41(11):932-936 (1991).  BE Janssens, et al., "New Antihistaminic N-Heterocyclic 4-Piperidinamines," J. Med. Chem., 28:1934-1943 (1985).  BF W. Ebert, "Soft Elastic Gelatin Capsules: A Unique Dosage Form," Pharm. Tech., 1(5):44-50 (1977).  BG S.M. Blaug, et al., "Interaction of Dextroamphetamine Sulfate with Spray-Dried Lactose," J. Pharm. Sci., 61(11):1770-1775 (1972).  BH R. Castello, et al., "Discoloration of Tablets Containing Amines and Lactose," J. Pharm. Sci., 51(2):106-108 (1962).   | -   |    | K.J. Hartauer, et al., "A Comparison of Diffuse Reflectance FT-IR Spectroscopy and D30 in all Characterization of a Drug-Excipient Interaction," Drug Development and Indus. Pharm., 17(4):617-630 |  |  |  |  |  |  |
| J. Med. Chem., 28:1934-1943 (1985).  BF W. Ebert, "Soft Elastic Gelatin Capsules: A Unique Dosage Form," Pharm. Tech., 1(5):44-50 (1977).  BG S.M. Blaug, et al., "Interaction of Dextroamphetamine Sulfate with Spray-Dried Lactose,"  J. Pharm. Sci., 61(11):1770-1775 (1972).  BH R. Castello, et al., "Discoloration of Tablets Containing Amines and Lactose,"  J. Pharm. Sci., 51(2):106-108 (1962).   |     | BD | Kamei, et al., "Antiallergic Effects of Major Metabolites of Astemizole in Rats and Guinea Pigs, Arzneimittel Forschung, 41(11):932-936 (1991).  |  |  |  |  |  |  |
| BG S.M. Blaug, et al., "Interaction of Dextroamphetamine Sulfate with Spray-Dried Lactose,"  J. Pharm. Sci., 61(11):1770-1775 (1972).  BH R. Castello, et al., "Discoloration of Tablets Containing Amines and Lactose,"  J. Pharm. Sci., 51(2):106-108 (1962).  |     | BE | 1. A. J. Cham. 28:1934-1943 (1985).  |  |  |  |  |  |  |
| BG S.M. Blaug, et al., "Interaction of Dextroamphetamine Sulfate with Spray-Dried Lactose,"  J. Pharm. Sci., 61(11):1770-1775 (1972).  BH R. Castello, et al., "Discoloration of Tablets Containing Amines and Lactose,"  J. Pharm. Sci., 51(2):106-108 (1962).  |     | BF | W. Ebert, "Soft Elastic Gelatin Capsules: A Unique Dosage Form," Pharm. Tech., 1(3),44-35 (1997)   |  |  |  |  |  |  |
| BH R. Castello, et al., "Discoloration of Tablets Containing Amines and Lactose," J. Pharm. Sci., 51(2):106-108 (1962).  |     | BG | S.M. Blaug, et al., "Interaction of Dextroamphetamine Sulfate with Spray-Dried Lactose,"  J. Pharm, Sci., 61(11):1770-1775 (1972).   |  |  |  |  |  |  |
| TO CONSIDER A  | 1   | вн | R. Castello, et al., "Discoloration of Tablets Containing Amines and Lactose,"   |  |  |  |  |  |  |
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